

PATENT COOPERATION TREATY

10455-1PCT
DG

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: JEFFREY G. SHELDON
SHELDON & MAK, INC.
225 SOUTH LAKE AVENUE
9TH FLOOR
PASADENA, CA 91101-3021

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

<p>To: JEFFREY G. SHELDON SHELDON & MAK, INC. 225 SOUTH LAKE AVENUE 9TH FLOOR PASADENA, CA 91101-3021</p>		<p>Date of Mailing (day/month/year) 22 SEP 1998</p>
<p>Applicant's or agent's file reference 10455-1PCT</p>		<p>IMPORTANT NOTIFICATION</p>
<p>International application No. PCT/US96/11300</p>	<p>International filing date (day/month/year) 03 JULY 1996</p>	<p>Priority Date (day/month/year) NONE</p>
<p>Applicant CERA, INC.</p>		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

<p>Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231</p>	<p>Authorized officer SUN UK KIM Telephone No. (703) 308-2350</p>
<p>Facsimile No. (703) 305-3230</p>	

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 10455-1PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US96/11300	International filing date (day/month/year) 03 JULY 1996	Priority date (day/month/year) NONE
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant CERA, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

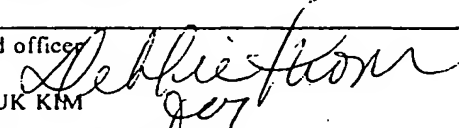
2. This REPORT consists of a total of 5 sheets.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 02 FEBRUARY 1998	Date of completion of this report 05 AUGUST 1998
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer  SUN UK KIM
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2350

I. Basis of the report

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

- ☐ the international application as originally filed.
- ☒ the description, pages (See Attached) , as originally filed.
pages _____ , filed with the demand.
pages _____ , filed with the letter of _____
pages _____ , filed with the letter of _____
- ☒ the claims, Nos. (See Attached) , as originally filed.
Nos. _____ , as amended under Article 19.
Nos. _____ , filed with the demand.
Nos. _____ , filed with the letter of _____
Nos. _____ , filed with the letter of _____
- ☒ the drawings, sheets/fig (See Attached) , as originally filed.
sheets/fig _____ , filed with the demand.
sheets/fig _____ , filed with the letter of _____
sheets/fig _____ , filed with the letter of _____

2. The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. STATEMENT**

Novelty (N)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO
Inventive Step (IS)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO
Industrial Applicability (IA)	Claims	<u>(Please See supplemental sheet)</u>	YES
	Claims	<u>(Please See supplemental sheet)</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-5, 9-11, 17, 21 and 24-25 lack an inventive step under PCT Article 33(3) as being obvious over Mehl in view of Markell et al. Mehl teaches method of using a filter for separating fluid samples comprising a microcolumn (12), a thin extraction media disc of particles (42) made of silica which are retained by upper and lower compression layers (44) made of glass fibers which inherently have a pore size less than the particle of the extraction media to retain particles (see figures 4-7; col. 2, lines 1-16; col. 3, lines 37-47; col. 4, line 61 - col. 5, line 55). Mehl also teaches that thickness of disc is 0.4 mm and diameter of disc is 4 mm and such specification of disc meets the claimed ratio of the effective diameter of the extraction media layer to the thickness of the layer (see col. 3, lines 37-47; col. 4, lines 61-64). Claims 1-5, 9-11, 17, 21 and 24-25 essentially differ from the method and apparatus of Mehl in reciting that the extraction media has a particle size of less than 20 microns. Markell et al teach an extraction media disk comprising particles having a size less than 20 microns (see col. 8, line 27 - col. 10, line 11). Incorporating particles having a size less than 20 microns in the extraction media of Mehl would have been obvious since such particles are known to be used for extraction process as taught in Markell et al.

Claim 26 lack novelty under PCT Article 33(2) as being anticipated by Pieper et al. Pieper et al teach a container (20, 22) having a thin layer of microparticulate extraction media (40) supported by upper and lower sheet (42, 44)(see col. 4, line 7 - col. 6, line 19).

Claims 6-8, 12-16, 18-20, 22-23 and 27-28 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest the apparatus for extracting a substance from a liquid sample including upper mesh flow distributor of claims 6-7, 18-19 and 28 and the lower mesh flow distributor of claims 8, 20 and 27 and the combination of the upper mesh flow distributor and the lower mesh flow distributor of claims 12 and 16. Claims 13-15 and (Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US96/11300

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1, 7 and 12 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims 1, 7 and 12 are indefinite for the following reason(s): Recitations of "the lower surface" in claims 1 and 12 and "the upper mesh flow distributor" in claim 7 lack positive antecedent basis.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(6): B01D 24/00, 24/12, 24/22, 25/00, 29/085, 29/39, 37/00, 39/02 and US Cl.: 210/198.2, 263, 283, 287, 289, 290, 291, 435, 446, 456, 483, 484, 488, 489, 490, 491, 502.1, 503, 505; 422/58, 59, 60, 69, 70, 101, 102, 104; 436/177, 178, 527; 530/412, 413, 416, 417; 502/401, 405

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
pages, 1-10, as originally filed.
pages, NONE, filed with the demand.
and additional amendments:
NONE

This report has been drawn on the basis of the claims,
numbers, 1-15, as originally filed.
numbers, NONE, as amended under Article 19.
numbers, NONE, filed with the demand.
and additional amendments:
Claims 16-28, filed with the letter of 04 August 1998.

This report has been drawn on the basis of the drawings,
sheets, 1-2, as originally filed.
sheets, NONE, filed with the demand.
and additional amendments:
NONE

V. 1. REASONED STATEMENTS:

The report as to Novelty was positive (YES) with respect to claims 1-28.
The report as to Novelty was negative (NO) with respect to claims 26.
The report as to Inventive Step was positive (YES) with respect to claims 6-8, 12-16, 18-20, 22-23, 27-28.
The report as to Inventive Step was negative (NO) with respect to claims 1-5, 9-11, 17, 21, 24-26.
The report as to Industrial Applicability was positive (YES) with respect to claims 1-28.
The report as to Industrial Applicability was negative (NO) with respect to claims NONE.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

22 depend on the novel and non-obvious claim 12. Claim 23 depends on the novel and non-obvious claim 16.

Claims 1-28 meet industrial applicability as defined by PCT Article 33(4) because the claimed subject matter can be made and/or used in industry.

----- NEW CITATIONS -----
NONE

PCT/US 76/11300
IPEA/US 04 AUG 1998

d) an upper mesh flow distributor above the upper compression layer and a lower mesh flow distributor below the lower compression layer sandwiching the compression layers and the layer of extraction media therebetween, the flow distributors holding the extraction media and the compression layers in the microcolumn, the upper compression layer distributing liquid sample uniformly across the top surface of the extraction media layer.

10

17. Apparatus for extracting an analyte from a liquid sample comprising:

a) a container having an entrance, an exit, and a passage therebetween for passage of a liquid sample containing an analyte therethrough, the container having a substantially flat bottom wall with the exit substantially centrally located therein;

b) within the passage, a thin layer of microparticulate extraction media for extracting the analyte from the liquid sample, wherein:

(i) the extraction media layer has a top surface, a bottom surface, and a peripheral edge,

(ii) the extraction media has a particle size of less than 20 microns,

(iii) the distance between the top and bottom surfaces of the extraction media layer is less than 1 mm, and

(iv) the extraction media layer is oriented in the passage so that liquid flows through the layer from its top surface to the bottom surface; and

c) an upper compression layer at the top surface of the extraction media layer and a lower compression layer at the lower surface of the extraction media layer, the two compression layers pressing the extraction media therebetween, the compression layers being sufficiently porous that the liquid sample can flow therethrough, the compression layers being formed of a

PCT/AL 11300
IPEN/05-13

flexible, hydrophilic, microfiber material and having a pore size less than the particle size of the extraction media.

5 18. The apparatus of claim 17 including an upper mesh flow distributor above the upper compression layer for distributing flow of the liquid sample through the extraction media.

10 19. The apparatus of claim 18 wherein the upper mesh flow distributor holds the compression layers and the extraction media layer in the microcolumn.

15 20. The apparatus of claim 18 including a lower mesh flow distributor below the lower compression layer.

20 21. A method of extracting a substance from a liquid sample comprising the step of passing the liquid sample into the entrance of the apparatus of claim 1 for transverse flow through the extraction media layer and out the exit, wherein the substance is extracted from the liquid sample by the extraction media.

25 22. A method of extracting an analyte from a liquid sample comprising the step of passing the liquid sample into the entrance of the apparatus of claim 12 for transverse flow through the extraction media layer and out the exit, wherein the analyte is extracted from the liquid sample by the extraction media.

30

23. A method of extracting an analyte from a liquid sample comprising the step of passing the liquid sample into the entrance of the apparatus of claim 16 for transverse flow through the extraction media layer and out the exit, wherein the analyte is extracted from the liquid sample by the extraction media.

24. A method of extracting an analyte from a liquid sample comprising the step of passing the liquid sample into the entrance of the apparatus of claim 17 for transverse flow through the extraction media layer and out the exit, wherein the analyte is extracted from the liquid sample by the extraction media.

25. The apparatus of claim 1 wherein the ratio of the effective diameter of the extraction media layer to the distance between its top and bottom surfaces is at least 10.

26. Apparatus for extracting a substance from a liquid sample comprising:

(a) a container having a top, a bottom, an entrance in the top, an exit in the bottom, and a passage between the entrance and exit for downward passage of a liquid sample therethrough, the bottom having an inner wall which is substantially flat with the exit being substantially centrally located in the bottom;

(b) within the passage, a thin layer of microparticulate extraction media for extraction of the substance from the liquid sample; and

(c) cylindrical support means for the extraction media layer, the support means having a flat upper surface and a flat lower surface, the support means being directly seated against the bottom inner wall and the extraction media layer being directly against the support means.

IPEA/US 04 AUG 1998

27. The apparatus of claim 26 wherein the support means comprises a lower compression layer at the lower surface of the extraction media layer and a lower mesh flow distributor below the lower compression layer.

5

28. The apparatus of claim 27 comprising an upper compression layer at the upper surface of the extraction media layer and an upper mesh flow distributor above the upper compression layer.